

## REMARKS

### Claim Rejections – 35 USC §§102 and 103

Claims 1-20, 28, 29, 33-42, 44-46 and 48-60 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,059,193 to Kuslich, and claims 21, 43 and 47 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich, and claims 22-27 have been rejected as being unpatentable over Kuslich in view of U.S. Patent No. 6,371,989 to Chauvin.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

The entire basis for rejection of pending independent claims 1, 33, 37, 45 and 50 as being anticipated by Kuslich is set forth in the Office Action as follows:

Kuslich discloses the claimed invention including using in a surgical procedure a body 12 having axial walls 26 interconnected at their ends and an expansion member 16, 20 co-acting with the walls to expand the body along a transverse axis. The body comprises the axial walls that comprise a rectangular cross-section. The expansion member comprises a component of axial displacement along a longitudinal axis of the device. The inner surfaces of the walls are arcuate or tapered and accordingly comprise a concave recessed area for receiving the expansion member. The walls outwardly deform to form a convex outer curvature. An inner chamber 116 is accessible via openings between the walls. The chamber is filled with bone growth promoting substance. The central portion of the body has a width that is greater than that of the ends. (See page 2; citations omitted).

\* \* \*

The device of Kuslich comprises the claimed structure. The expansion member is an internal support, positioned within an inner chamber and engaging inner surfaces of the axial walls. Moreover, when the device is expanded, some sliding movement would occur between the expansion member and walls. The expansion member can also be said to be uni-axial because it is actuated along a single axis. (See page 4).

As an initial matter, the rejection of each of the pending independent claims as being anticipated by Kuslich is based, in large part, on the assertion that the inner tubular structure 20 is part of the expander 14. However, Kuslich teaches that the inner tubular structure 20 is part of the implant body 12, and not the expander 14. (See col. 3, l. 30-60). Indeed, Kuslich expressly teaches that the inner tubular structure 20 and the outer tubular structure 22 “are joined into a completed assembly 60, as shown in FIG. 13. Assembly 60 is formed by sliding inner structure 20 into outer structure 22 as shown in FIG. 12. Inner structure 20 is adhered to the inner surface of outer structure 22 through any suitable mean, such as adhesives or the like.” (See col. 5, l. 66 to col. 6, l. 3; emphasis added). In summary, Kuslich discloses that the inner and outer tubular structures 20, 22 are joined together to form an integrated/composite implant body 12. (See col. 4, ll. 59-64). Accordingly, the Applicant submits that the assertion set forth in the Office Action that the inner tubular structure 20 is part of the expander 14 (which constitutes the primary basis for rejection of each of the pending independent claims) is incorrect.

Furthermore, the Applicant maintains that the implant expander 14 of Kuslich does not engage central portions of the axial walls of the implant body 12. Instead, the implant expander 14 includes end caps 18, 32 that engage the end rings 23 of the implant body 12, and which are drawn together to exert an axial compressive force onto the end rings 23 to expand the implant body 12. Indeed, no portion of the expander 14 is in any way engaged with the axially-extending ribs of the implant body 12 at a location intermediate the end rings 23. Likewise, no portion of the expander 14 in any way extends transversely between and engages central portions/mid-portions of the axially-extending ribs to expand the implant body 12. This is clearly illustrated in Figures 2, 2B and 24 of Kuslich. Moreover, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, the axially-extending ribs 28 do not extend transversely between central portions of the axially-extending ribs 26 of the outer tubular structure 22. Instead, the inner ribs 28 are joined securely to and extend axially along the outer ribs 26, and do not extend transversely between central portions of the outer ribs 26.

For at least the reasons set forth above, the Applicant submits that the pending independent claims are not anticipated by Kuslich. Nevertheless, as set forth below, additional reasons support the patentability of the pending independent claims over the cited references.

### **Claim Amendments**

Claims 8, 9, 40, 41 and 48 have been rewritten in independent form, and independent claims 1, 37 and 45 have been cancelled without prejudice for possible submission in a continuing application. Additionally, dependent claims 2, 4, 5, 7, 22, 28 and 29 have been amended to depend from rewritten independent claim 8, dependent claim 17 has been amended to depend from rewritten independent claim 9, dependent claims 38 and 42 have been amended to depend from rewritten independent claim 41, and dependent claims 46 and 47 have been amended to depend from rewritten independent claim 48.

The Applicant notes that independent claims 8, 9, 40, 41 and 48 have each been rewritten in independent form, but the scope of these claims has not in any way changed. The Applicant therefore submits that rewritten claims 8, 9, 40, 41 and 48 in independent form do not raise any new issues that would require further consideration or searching. The remaining claim amendments merely change the dependencies of various claims originally depending from cancelled independents claims 1, 37 and 45 to corresponding ones of the rewritten independent claims 8, 9, 40, 41 and 48.

### **Rewritten Independent Claims 8, 9, 40, 41 and 48**

Rewritten independent claims 8, 9, 40, 41 and 48 each recite “said expansion member comprising an internal support member positioned within a central region of said inner chamber and having a height extending transversely between and engaging opposing inner surfaces of said central portions of said first and second axial walls”. As shown most clearly in Figures 2, 2B and 23 of Kuslich, the implant 10 does not include any structure or element that could reasonably be construed as an internal support member positioned within a central region of the interior of the implant body 12 and having a height extending transversely between and engaging opposing inner surfaces of central portions of the axially-extending ribs 26, 28. Indeed, the only structure positioned within the central region of the interior of the implant body 12 is the tie rod 16 of the expander 14. However, the tie rod 16 does not have a height that extends transversely between and engages opposing inner surfaces of the central portions of the axially-extending ribs 26, 28. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, the

inner axially-extending ribs 28 likewise do not constitute an internal support member having a height that extends transversely between and engages opposing inner surfaces of the central portions of the outer axially-extending ribs 26. Moreover, the Office Action does not set forth any grounds or rational whatsoever as to how the Kuslich implant satisfies these recited elements and features. Indeed, the Office Action does not even mention or refer to the term “height”. Accordingly, a *prima facie* case of anticipation has not been established with regard to rewritten independent claims 8, 9, 40, 41 and 48.

Additionally, providing an internal support member positioned within a central region of the inner chamber of the implant body which has a height extending transversely between and engaging opposing inner surfaces of central portions of the axial walls not only serves to expand the implant body, but also provides transverse support to the axial walls at a central location of the implant to resist compression loading onto the implant body by the adjacent vertebrae, and to provide structural stability and rigidity to the implant body. Indeed, as set forth in paragraph 56 of the published version of the subject application, “positioning of the expansion pin 24 within the center compartment 90c of the inner chamber 40 provides additional support and rigidity to the upper and lower walls 30, 32 of the fusion cage 22 to resist compression loads from the vertebral bodies  $V_U$ ,  $V_L$ , particularly near the central portion 22c of the fusion cage 22 which is otherwise devoid of internal support members.” However, the Kuslich implant fails to provide any type of transverse support member at a central region of the implant interior that is engaged between central portions of the axially-extending ribs 26. Instead, the Kuslich implant relies solely on the axial compressive force exerted onto the end rings 23 of the implant body 12 to expand the implant body and to resist vertebral loading.

Furthermore, rewritten independent claim 8 recites that “said expansion member cooperates with said first and second axial walls to uni-axially expand said body along said transverse axis”. Additionally, rewritten independent claim 41 similarly recites that “said expansion member cooperates with said first and second axial walls to outwardly deform and uni-axially expand said first and second axial walls along said transverse axis”, and rewritten independent claim 48 similarly recites that “expansion of said body comprises outward deformation and uni-axial expansion of said first and second axial walls along said transverse axis”. Figures 6 and 7 of the subject application clearly illustrate the expansion member 24

cooperating with the axial walls 30, 32 to uni-axially expand the implant body 22 along a single transverse axis T.

With regard to Kuslich, as should be readily apparent, the implant body 12 is expanded along multiple axes to provide a spherical-shaped expanded implant configuration (see Figure 1). Since the implant body 12 expands along multiple axes to provide the spherical-shaped configuration, the implant body does not uni-axially expand along a single transverse axis, as recited in rewritten independent claims 8, 41 and 48. The Office Action asserts that “the expansion member can also be said to be uni-axial because it is actuated along a single axis. (See page 4; emphasis added). The Applicant notes that rewritten independent claims 8, 41 and 48 specifically recite that the first and second axial walls are uni-axially expanded along said transverse axis. However, the Kuslich implant body 12 is clearly expanded along multiple axes to provide a spherical-shaped expanded implant configuration shown in Figure 1. Kuslich does not in any way disclose or suggest that the implant body 12 is uni-axially expanded along a single transverse axis T, as recited in rewritten independent claims 8, 41 and 48. Accordingly, a *prima facie* case of anticipation has not been established with regard to rewritten independent claims 8, 41 and 48 for these additional reasons as well.

Additionally, rewritten independent claims 9 and 40 recites that “said movement of said expansion member within said inner chamber comprises axial displacement generally along said longitudinal axis, said expansion member slidably engaged along opposing inner surfaces of said first and second axial walls during said axial displacement”.

With regard to Kuslich, the implant body 12 is not expanded by slidably engaging any portion of the expander 14 (including the tie rod 16 and the end caps 18 and 32) “along opposing inner surfaces” of the axially-extending ribs 26, 28 in an axial direction. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, as indicated above, Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined together to form an integrated/composite implant body 12. Specifically, Kuslich expressly discloses that the inner tubular structure 20 and the outer tubular structure 22 “are joined into a completed assembly 60, as shown in FIG. 13. Assembly 60 is formed by sliding inner structure 20 into outer structure 22 as shown in FIG. 12. Inner structure 20 is adhered to the inner surface of outer structure 22

through any suitable mean, such as adhesives or the like.” (See col. 5, l. 66 to col. 6, l. 3; emphasis added). In summary, Kuslich discloses that the inner and outer tubular structures 20, 22 are joined together to form an integrated/composite implant body 12. (See col. 4, ll. 59-64).

The Applicant submits that the assertion set forth in the Office Action that the “when the device is expanded, some sliding movement would occur between the expansion member and walls” is incorrect. (See page 4). Indeed, since Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined/adhered together to form an integrated/composite implant body 12, there would be no sliding engagement of the inner tubular structure 20 along opposing inner surfaces of the outer tube 22. Contrary to the assertion set forth in the Office Action, no portion of the inner tubular structure 20 is in any way slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12. Furthermore, as indicated above, no portion of the expander 14 is slidably engaged along opposing inner surfaces of the inner or outer tubular structures 20, 22 during expansion of the implant body. As a result, further reasons exist as to why rewritten independent claims 9 and 40 are not anticipated by Kuslich. Accordingly, a *prima facie* case of anticipation has not been established with regard to rewritten independent claims 9 and 40 for these additional reasons as well.

For at least the reasons set forth above, rewritten independent claims 8, 9, 40, 41 and 48 are not anticipated by Kuslich. Therefore, withdrawal of the rejection of rewritten independent claims 8, 9, 40, 41 and 48 and allowance of the same is respectfully requested.

### **Independent Claim 33**

Independent claim 33 recites that “said axial walls and said transverse end walls defining generally flat and planar upper and lower vertebral bearing surfaces extending substantially entirely across said implant width”. With regard to Kuslich, the implant body 12 has a cylindrical configuration, and the outer surfaces defined by the end rings 23 and the axially-extending ribs 26 of the implant body 12 are each circular, and clearly do not define “generally flat and planar upper and lower vertebral bearing surfaces” that extend “substantially entirely across” the width of the implant body 12. Even assuming arguendo that a single/individual rib 26 could be construed to have a generally flat and planar upper/lower bearing surface, the

Applicant notes that the entire implant body 12 must be construed to have generally flat and planar upper and lower vertebral bearing surfaces extending substantially entirely across said implant width, as recited in independent claim 50. The Applicant submits that the implant body 12 of Kuslich clearly does not satisfy these features. Indeed, to find otherwise would entirely disregard and ignore the cylindrical configuration of the implant body when in the non-expanded state and the spherical configuration of the implant body when in the expanded state.

For at least the reasons set forth above, a *prima facie* case of anticipation has not been established with regard to rewritten independent claim 33. Accordingly, withdrawal of the rejection of the independent claim 33 and allowance of the same is respectfully requested.

### **Independent Claim 50**

Independent claim 50 recites the step of “expanding the intervertebral implant along the transverse axis by slidably engaging the expansion member along opposing inner surfaces of the first and second axial walls in a direction along the longitudinal axis to a location intermediate the first and second transverse end walls with the expansion member extending transversely between and engaging mid-portions of the first and second axial walls”. As indicated above with regard to rewritten independent claims 9 and 40, the implant body 12 of Kuslich is not expanded by “slidably engaging” any portion of the expander 14 (including the tie rod 16 and the end caps 18 and 32) “along opposing inner surfaces” of the axially-extending ribs 26, 28 in an axial direction. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, as indicated above, Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined together to form the integrated/composite implant body 12. Accordingly, no portion of the inner tubular structure 20 is slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12.

The Applicant submits that the assertion set forth in the Office Action that the “when the device is expanded, some sliding movement would occur between the expansion member and walls” is clearly incorrect. (See page 4). Indeed, since Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined/adhered together to form an integrated/composite implant body 12, there would be no sliding engagement of the inner tubular

structure 20 along opposing inner surfaces of the outer tube 22. Contrary to the assertion set forth in the Office Action, no portion of the inner tubular structure 20 is in any way slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12. Furthermore, no portion of the expander 14 is slidably engaged along opposing inner surfaces of the inner or outer tubular structures 20, 22 during expansion of the implant body.

For at least the reasons set forth above, a *prima facie* case of anticipation has not been established with regard to rewritten independent claim 50. Accordingly, withdrawal of the rejection of the independent claim 50 and allowance of the same is respectfully requested.

**Dependent Claims 2-7, 10-29, 34-36, 38, 39, 42-44, 46, 47, 49 and 51-60**

Dependent claims 2-7, 10-29, 34-36, 38, 39, 42-44, 46, 47, 49 and 51-60 depend either directly or indirectly from independent claims 8, 9, 33, 40, 41, 48 or 50, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims. However, further reasons exist in support of the patentability of the dependent claims.

For example, dependent claims 29 and 34 recite “said expansion member slidably engaged along opposing inner surfaces of said first and second axial walls during said axial displacement”. However, as indicated above with regard to independent claims 9 and 40, no portion of the expander 14 (including the tie rod 16 and the end caps 18 and 32) is slidably engaged along opposing inner surfaces of the axially-extending ribs 26, 28 to expand the implant body 12 along a transverse axis. Furthermore, even assuming *arguendo* that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, as indicated above, Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined together to form the integrated/composite implant body 12. Accordingly, no portion of the inner tubular structure 20 is slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12 along a transverse axis.

Dependent claim 35 recites that “said expansion member comprises an internal support member positioned within a central region of said inner chamber and having a height extending



transversely between and engaging opposing inner surfaces of said central portions of said first and second axial walls”, and dependent claim 52 recites that “the expansion member comprises an internal support member positioned within a central region of the inner chamber and having a height extending transversely between and engaging the opposing inner surfaces of the mid-portions of the first and second axial walls”. As indicated above with regard to rewritten independent claims 8, 9, 40, 41 and 48, Kuslich fails to disclose these recited features.

Dependent claim 53 recites “wherein moving the expansion member within the central portion of the inner chamber results in uni-axial expansion of the first and second axial walls along the transverse axis”. However, as indicated above with regard to rewritten independent claims 8, 41 and 48, the implant body 12 of Kuslich is expanded along multiple axes to provide a spherical-shaped expanded implant configuration (see Figure 1). Since the implant body 12 expands along multiple axes to provide the spherical-shaped configuration, the implant body does not uni-axially expand along a single transverse axis.

## CONCLUSION

The Applicant respectfully requests entry of this response to the final Office Action and consideration and allowance of the present application including pending claims 2-29, 33-36, 38-44 and 46-60. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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